

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
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Reinhard BOLLI *et al.*) Group Art Unit: 1644
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Application No.: 10/579,357) Examiner: Yunsoo KIM
)
Filed: May 16, 2006) Confirmation No.: 2138
)
For: IMMUNOGLOBULIN)
PREPARATIONS HAVING)
INCREASED STABILITY)

VIA EFS WEB

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Office the documents on the attached SB-08 form. This Information Disclosure Statement is being filed before the mailing date of a first Office Action after the filing of the Request for Continued Examination on September 3, 2009.

Copies of the U.S. patent publications are not enclosed. Copies of the listed foreign and non-patent literature documents are attached.

With respect to the non-English language documents, Applicants submit the following remarks:

1. **DE 2 364 792** - An abstract of the disclosure of this document can be found in the English language Derwent abstract submitted herewith.

2. **DE 3 430 320 A1** - An abstract of the disclosure of this document can be found in the English language Derwent abstract submitted herewith.

3. **DE 4 118 912 C1** - An abstract of the disclosure of this document can be found in the English language Derwent abstract submitted herewith.

4. **EP 0 447 585 B1** - This document is believed to be related to U.S. Patent No. 5,164,487 cited on the attached Form PTO/SB/08.

5. **WO 94/29334** - This document is believed to be related to U.S. Patent No. 6,069,236, cited on the attached Form PTO/SB/08.

6. **Gammagard S/D**, "Humanes Immunoglobulin Zur Intravenösen Anwendung Solvent'Detergetn Behandelt," Product Information from February 1994, Baxter Deutschland GmbH, Edisonstr. 3-4, D-85716 Unterschleißheim, Germany. A brief statement as to the contents of this document is provided below:

The Gammagard S/D document is a technical brochure describing Gammagard S/D, a lyophilized IgG product sold by Baxter in Germany. According to the document the lyophilized IgG product contains 1.0 g IgG, 0.45 g glycine, 0.43 g glucose monohydrate, 0.232 g NaCl, 0.06 g human albumin protein, 0.04 g polyethyleneglycol. This lyophilized product is reconstituted in 20 mL sterile water. (See page 8.) The document also discusses the amounts of IgG subclasses in the product and the amounts of contaminants such as IgA, infectious viruses, and the like. It also includes a table showing the antibody make-up of the IgG product. It also discusses chromatography methods of purifying IgG molecules, as well as the pharmacokinetics, pharmacodynamics, and clinical results for the product.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Office applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

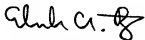
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: September 24, 2009

By: 
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